

Exhibit D

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

In Re: Bard IVC Filters) MD-15-02641-PHX-DGC
Products Liability Litigation)
) Phoenix, Arizona
) March 27, 2018
)

Sherr-Una Booker, an individual,)
)
Plaintiff,)
) CV-16-00474-PHX-DGC
v.)
)
C.R. Bard, Inc., a New Jersey)
corporation; and Bard Peripheral)
Vascular, Inc., an Arizona)
corporation,)
)
Defendants.) Amended
_____)

BEFORE: THE HONORABLE DAVID G. CAMPBELL, JUDGE

REPORTER'S AMENDED TRANSCRIPT OF PROCEEDINGS

TRIAL DAY 9 A.M. SESSION

(Pages 1876 - 2000)

Official Court Reporter:
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Proceedings Reported by Stenographic Court Reporter
Transcript Prepared with Computer-Aided Transcription

08:41:32 1 the letter in light of the overall facts at trial.

2 My conclusion, now that I've heard the evidence, is
3 that Section 3 of the warning letter is relevant to this case.
4 I reach that conclusion for a few reasons:

08:41:50 5 The argument that was made by the defendants in the
6 brief was largely a causation argument, that none of the
7 complaints could have caused Ms. Booker's injuries because
8 they were either after the implant or the doctors who removed
9 the filter had no knowledge of those complaints.

08:42:07 10 I agree with that. I don't think it goes to
11 causation. But I think the relevancy of Section 3 of the
12 warning letter goes to a few other issues that have been
13 addressed.

14 There has been much evidence before the jury about
08:42:23 15 the MAUDE database, about the data upon which Bard relied,
16 upon reports to the FDA. There has been evidence about root
17 cause analysis and when it was or was not done. There has
18 been evidence about the fact that the FDA has not submitted
19 questions, other than those that were identified in documents
08:42:46 20 that were put in evidence, has not taken recall action.

21 I believe the implication, if not the express
22 argument to the jury, is that the FDA never took any action
23 with respect to Bard.

24 And yet Section 3 of this letter does concern Bard's
08:43:05 25 handling and reporting of adverse events with respect to the

08:43:09 1 G2 filter in at least four different instances, as well as the
2 adequacy of Bard's evaluation for root cause of the
3 violations. Root cause is in Section 3A, the G2 filter is
4 mentioned in Section 3B. 3C includes other filters which
08:43:29 5 apparently largely are unidentified, but which plaintiffs at
6 least assert includes one G2 filter.

7 I think it's relevant in light of the information
8 that's been presented to the jury. And, therefore, I'm going
9 to permit the following portions of the G2 letter to be
08:43:45 10 presented:

11 Page 1, which is largely introductory information.

12 Page 4, starting with the heading "Quality System
13 Regulation Violations of Tempe, Arizona Facility and
14 Queensbury, New York Facility." That heading can be included,
08:44:07 15 as can the rest of the page, which is Section 3.

16 Page 5 through the end of the third paragraph. So it
17 should not include the heading "Quality System Regulation
18 Violations at Queensbury, New York," which is a different set
19 of violations.

08:44:24 20 So that essentially leaves in all of Section 3.

21 And page -- the version of the exhibit I have
22 actually has the page numbers out of order.

23 Page 10, beginning with the paragraph at the bottom
24 that reads "Your firm should take prompt action to correct the
08:45:17 25 violations addressed in this letter," that paragraph at the